



1. VETERINARY MEDICATION NAME

Rx Spectrum® Enrofloxacin 50 mg

2. PHARMACEUTICAL PRESENTATION

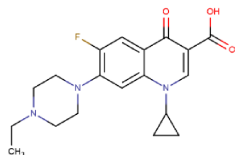
Tablets

3. FORMULA

Each tablet contains:

Enrofloxacin	50 mg
Excipient q.s.	1 tablet

4. STRUCTURAL FORMULA



5. THERAPEUTIC INDICATIONS

Broad-spectrum antimicrobial for the treatment of infections caused by microorganisms susceptible to enrofloxacin in the following cases:

Respiratory system: pharyngitis, laryngitis, tracheitis, bronchitis, tracheobronchitis, pneumonia, bronchopneumonia and kennel cough.

Digestive tract: leptospirosis, bacterial gastroenteritis, bacterial peritonitis and stomatitis.

Genitourinary: cystitis, prostatitis, urethritis, pyometritis, vaginitis, metritis and kidney infections.

Dermatological: abscesses, wounds, pyodermas and soft tissue infections, as well as otitis, osteoarticular infections and septicemia in general.

6. SPECTRUM

Active against gram positive bacteria, gram negative bacteria, including: *Pasteurella* spp., *Staphylococcus* spp., *Pseudomonas aeruginosa*, *Klebsiella* spp., *Escherichia coli*, *Mycobacterium* spp., *Proteus* spp. and *Salmonella* spp. Relatively ineffective against obligate anaerobes. Has effect against *Mycoplasma* spp. (BSAVA, 2017).

7. SPECIES

Canines and felines (Plumb, 2008).

8. ADMINISTRATION ROUTE

Oral.

9. DOSAGE

General dosage:

Canines: 5 to 20 mg/kg (22.2 lb) of body weight every 24 hours.

Felines: 5 mg/kg (2.2 lb) body weight, every 24 hours. (Plumb, 2008).

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Canines and felines: 1 tablet per 10 kg of body weight (approximately 1 tablet per 22 lb), every 24 hours for 5 consecutive days or until clinical signs resolve, not to exceed 30 days of treatment.

The dosage may be adjusted at the discretion of the Veterinarian.

10. MECHANISM OF ACTION

It acts by inhibiting DNA gyrase (a type II topoisomerase), thereby preventing the supercoiling of genetic material and the aggregation of nucleotides, thus blocking bacterial DNA synthesis. The activity of enrofloxacin is bactericidal and concentration-dependent: the death of susceptible microorganisms occurs within 20 to 30 minutes of exposure. Enrofloxacin has been shown to exhibit a significant post-antibiotic effect against both Gram-negative and Gram-positive bacteria (Marín, 2015; Plumb, 2008).

11. PHARMACOKINETICS

Enrofloxacin has an oral bioavailability of approximately 53% in monogastric animals. It can accumulate in phagocytes and appears to exert a measurable immunostimulatory effect. At an oral dose of 5 mg/kg (2.2 lb), the reported maximum plasma concentration (C_{max}) is 0.3 µg/mL, reached at approximately 4 hours post-administration (T_{max}). It is primarily eliminated through biliary excretion and hepatic biotransformation with subsequent biliary excretion. Its elimination half-life is approximately 3.7 hours. The primary metabolic pathways include dealkylation, glucuronidation, oxidation, sulfoxidation, acetylation, and piperazine ring cleavage. One of the metabolites is ciprofloxacin, and the combined action of enrofloxacin and ciprofloxacin appears to produce a complementary antibacterial effect. It concentrates in the urinary tract, where it is excreted through glomerular filtration for the unbound fraction, as well as via active tubular secretion. It has also been reported that a portion is eliminated through gastrointestinal secretions (Sumano *et al.*, 2015).

12. WARNINGS

Enrofloxacin is contraindicated in small to medium breed dogs between 2 and 8 months of age, as it may cause cartilage damage in growing animals. It may cause CNS stimulation, so it should be used with caution in patients with seizure disorders.

Patients with severely impaired renal or hepatic function may require dose adjustment to avoid intoxication (Küng *et al.*, 1994; Plumb, 2008).

Incorrect use of this product may cause bacterial resistance.

13. ADVERSE REACTIONS

In dogs, the following adverse effects have been infrequently reported: ataxia, seizures, depression, lethargy, nervousness, hypersensitivity, and crystalluria. Cats treated with enrofloxacin may experience: vomiting, anorexia, diarrhea, weight loss, ataxia, seizures, depression, lethargy, vocalization and aggression (Plumb, 2008).

14. OVERDOSAGE

Common findings in dogs (in decreasing order of frequency) included: vomiting, diarrhea, seizures, ataxia and fasciculation. Findings recorded in cats (in decreasing order of frequency) included: seizures, vomiting and blindness (Plumb, 2008).

15. DRUG INTERACTIONS

Products containing cations, as well as iron and zinc (administered orally) can bind to enrofloxacin and prevent its absorption.

Sucralfate inhibits the absorption of enrofloxacin.

In dogs, flunixin has been observed to increase the AUC and elimination half-life of enrofloxacin, and enrofloxacin, in turn, increases the AUC and elimination half-life of flunixin.

Synergism may occur with antibiotics such as aminoglycosides, third generation cephalosporins and broad-spectrum penicillins.

May exacerbate nephrotoxicity and reduce cyclosporine metabolism.

Enrofloxacin can increase: theophylline blood levels, warfarin effects and alter phenytoin and methotrexate levels; resulting in toxicity (Plumb, 2008).

16. INTERACTIONS WITH LABORATORY TESTS

It may cause an elevation of liver enzymes and produce false-positive results in urinary glucose determination when using the copper sulfate method (Plumb, 2008).

17. USE DURING PREGNANCY AND/OR LACTATION

Its use is not recommended during gestation or lactation, due to the negative effect it has on the cartilage of young animals (Plumb, 2008).

18. PRECAUTIONS

Store in a cool, dry place away from direct sunlight and/or heat.

Keep out of reach of children and pets. Product for exclusive use in Veterinary Medicine.

19. EXPIRATION PERIOD

Shelf life of the veterinary medicinal product as packaged for sale: 24 months.

20. HOLDER OF THE REGISTRY

HOLLAND DE MEXICO SA DE CV
Calle 21 Este No 12, Col. Civac
Jiutepec, Morelos, CP 62578

21. REGISTRATION NUMBER

Q-4196-151

22. SALE, DISPENSATION, AND/OR USE PROHIBITION

Prescription required.

Consult your veterinarian.

23. PRESENTATION

Box with 10 tablets.

24. REFERENCES

- 24.1 BSAVA. Small Animal Formulary, Part A: canine and feline. 9th ed.UK. 2017.
- 24.2 Küng *et al.* Pharmacokinetics of baytril (enrofloxacin) in dogs. Schweiz Arch Tierheilkd. 1994; 136 (10):329-334.
- 24.3 Marin H. Practical Pharmacology in Cats. Mexico, 2016.
- 24.4 Plumb, D. Veterinary Drug Handbook. Sixth Edition, Blackwell Publishing, Iowa, 2008.
- 24.5 Sumano *et al.* Veterinary Pharmacology. 4th ed. Mexico, 2015.

CERTIFICATE OF ACCURACY

I, the undersigned, Diana Alicia de Regules Silva, Certified Translator No. P037-2020 SPANISH-ENGLISH-SPANISH, duly sworn and authorized by the Mexican Supreme Court of Justice, as per the Federal Judiciary Council's publication in the Federal Official Gazette on December 11, 2024 (accessible at https://www.dof.gob.mx/2024/CJF/listado_peritos_PJF_2025.pdf page 204):

1. I hereby certify that I have translated a **2**-page document in Spanish, titled **"FICHA TÉCNICA"** into a **2**-page English document, titled **"TECHNICAL DATA SHEET"** both of which are attached herewith.



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